



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1140

[Docket No. FDA-2011-N-0493]

RIN 0910-AG40

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to
Protect Children and Adolescents

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the Agency's regulations to allow the manufacturer of a cigarette or smokeless tobacco product with a trade or brand name that is also the trade or brand name of a nontobacco product to continue to use the name if the tobacco product was sold in the United States on or before June 22, 2009. FDA further proposes to amend the Agency's regulations to ensure that a manufacturer of a cigarette or smokeless tobacco product may continue to use its trade or brand name even if that name is subsequently registered with the United States Patent and Trademark Office (USPTO) or subsequently used for a nontobacco product.

DATES: Submit either electronic or written comments by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. FDA-2011-N-0493 and/or RIN 0910-AG40 by any of the following methods:

Electronic Submissions:

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions:

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name, Docket No. FDA-2011-N-0493, and RIN 0910-AG40, for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Public Law 111-31) (Tobacco Control Act) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 et seq.) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors.

Section 102 of the Tobacco Control Act required FDA to publish a final rule regarding cigarettes and smokeless tobacco identical in its provisions to the “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents” (61 FR 44396, August 28, 1996) (1996 final rule), with certain specified exceptions. None of the specified exceptions affect the substance of § 897.16(a) (21 CFR 897.16(a)) of the 1996 final rule. Thus, § 1140.16(a) (21 CFR 1140.16(a)) in the reissued 1996 final rule is identical to § 897.16(a) of the 1996 final rule: “Restriction on product names. A manufacturer shall not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except for a tobacco product whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995.”

This provision, like other provisions in the 1996 final rule, was intended to ensure that the restrictions on sale and distribution to children and adolescents were not undermined by how the product was presented to the public (61 FR 44396 at 44444). If a manufacturer was permitted to use a popular nontobacco product trade name and put it on a tobacco product, the manufacturer could attempt to exploit the imagery or consumer identification attached to the nontobacco product to make the tobacco product appeal to young people (Id.).

FDA included the January 1, 1995, date in § 897.16(a) of the 1996 final rule so that the restriction would not apply to cigarette and smokeless tobacco products that already were using trade or brand names that were also on nontobacco product (60 FR 41314 at 41324 (August 11, 1995), 61 FR 44396 at 44444)). FDA's intent was to prospectively prohibit tobacco manufacturers from using nontobacco trade or brand names, whether used on tangible products or for services, on cigarettes and smokeless tobacco products (Id.).¹ Thus, the section permitted manufacturers to continue using a nontobacco trade or brand name for its cigarettes or smokeless tobacco product if the name was on both a tobacco product and a nontobacco product sold in the United States on or before January 1, 1995 (61 FR 44396 at 44444).

FDA also intended that this provision of the 1996 final rule would apply only to trade names in use in the United States (61 FR 44396 at 44445). In the preamble to the 1996 final rule, FDA acknowledged that it would be unreasonable for the regulations to encompass all possible nontobacco product trade names, regardless of their nationality or whether the trade name was a registered trademark. Neither FDA nor manufacturers would be able to ensure that the name was not used outside the United States.

¹ FDA intended to construe this grandfather exception narrowly such that, if the trade or brand name of a pre-existing nontobacco product was "Old Time Country Store," the grandfather exception would not apply to a cigarette product called "Old Time" because "Old Time" was not identical to the name of the pre-existing nontobacco product (61 FR 44396 at 44445).

FDA is proposing to amend § 1140.16(a) to change the grandfather date from January 1, 1995, to June 22, 2009, in recognition of the fact that 14 years elapsed since the publication of the 1996 final rule. Using the January 1995 date significantly changes § 1140.16(a), from a provision that was intended to apply prospectively to one that applies retroactively. The proposed rule would amend the section to allow cigarettes and smokeless tobacco products sold in the United States on or before June 22, 2009, to continue to be sold under their trade or brand name, even if the trade or brand name was also used for a nontobacco product sold during that time. Thus, the proposed amendment would restore the FDA's original intention that the restriction apply prospectively only.

FDA is also proposing to amend § 1140.16(a) to ensure that a manufacturer may continue to use the trade or brand name of its cigarette or smokeless tobacco product if the trade or brand name is later registered with the USPTO or used on a nontobacco product.² Thus, a tobacco manufacturer would not be required to monitor whether a trade or brand name is registered for a nontobacco product after it initiates the sale of its tobacco product under a particular trade or brand name. In order to ensure that tobacco companies can comply with, and FDA can enforce, the proposed restriction, the proposed amendment would make explicit that the prohibition on the use of a nontobacco trade or brand name turns on whether such name is "registered," that is, whether it is listed in the USPTO's registration listing. FDA believes that this proposed change is consistent with the intent of the provision as originally issued in 1996 to prevent tobacco product manufacturers from exploiting the imagery and consumer identification associated with the trade or brand name of a nontobacco product. Thus, the provision should apply to situations where the use of the trade or brand name on the nontobacco product precedes the sale of a

² USPTO registers trade or brand names for both goods and services.

tobacco product with the same trade or brand name and should not restrict trade or brand names of tobacco products in other situations.

In addition, FDA is proposing to amend § 1140.16(a) to permit manufacturers to request an exemption from the restriction based on information that adequately demonstrates that their proposed trade or brand name does not substantially appeal to children or adolescents. The goal of the restriction is to ensure that manufacturers cannot exploit the imagery or consumer identification attached to the nontobacco product to make the tobacco product appeal to young people. If the manufacturer demonstrates in a written submission to the Director of FDA's Center for Tobacco Products that the proposed name (e.g., through the associated imagery or consumer identification attached to the nontobacco product) does not have substantial appeal to young people, then the potential for such exploitation is unlikely and the request for an exception would be granted.

As originally proposed, and as amended, the restriction on product names is intended to limit the sales and distribution of cigarettes and smokeless tobacco to children and adolescents. The State's interest in preventing the use of tobacco products by minors is well established. FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 161 (2000) (“[FDA] has amply demonstrated that tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States.”); Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 564 (2001) (“The State's interest in preventing underage tobacco use is substantial, and even compelling.”). The proposed restriction on the use of nontobacco product names provides a reasonable means to effect the goal of preventing the use of tobacco in minors.

Tobacco use continues to be the single leading preventable cause of death and disease in the United States (Ref. 1). More than 80 percent of established adult smokers begin smoking

before age 18 years (Ref. 1) and, of those adolescents who continue to smoke regularly, approximately 50 percent will die from smoking-attributable disease (Ref. 2). Among children, data from the 2009 Youth Risk Behavior Survey, a nationally representative survey of students in grades 9 through 12 in the United States, showed that almost half (46.3 percent) of U.S. high school students had tried cigarette smoking, and an estimated 19.5 percent of students were current cigarette smokers (Ref. 3). Overall, approximately 7.3 percent of high school students in 2009 were frequent cigarette users, and 11.2 percent of students under the age of 18 had been daily smokers at some point during their lifetime. Furthermore, followup studies of youth smokers have indicated that a significant number of students who are light smokers (i.e., students who are not daily smokers or who smoke less than 10 cigarettes per day) in high school will become heavy smokers after leaving high school (Ref. 4). In 2009, nearly 9 percent of high school students used a smokeless tobacco product (e.g., chewing tobacco, snuff, or dip) (Ref. 5). The Surgeon General reports that adolescents who use smokeless tobacco are more likely than nonusers to become cigarette smokers (Ref. 5).

Research supports the conclusion that tobacco advertising and promotion contribute to youth smoking initiation (Refs. 6 at p. 131, 7, 8, 9, and 10). The cigarette industry spends billions of dollars on advertising and promotion each year (Ref. 11). The National Cancer Institute (NCI) Monograph 19 stated that “tobacco advertising forms part of an integrated marketing communications strategy combining sponsorship, brand merchandising, brand stretching, packaging, point-of-sale promotions, and product placement” (Ref. 12 at p. 7). With respect to marketing tobacco to children and adolescents, Monograph 19 concluded among other things, that: (1) Tobacco advertising targets the psychological needs of adolescents (e.g., popularity) and “adolescents who believe that smoking can satisfy their psychological needs, or

whose desired image of themselves is similar to their image of smokers, are more likely to smoke cigarettes” and (2) even brief exposure to tobacco advertising influences adolescents’ intentions to smoke (Ref. 12 at pp. 280 and 281).

Brand equity, which consists of company name, brand, symbols, and slogans, and their underlying associations, is a primary source of competitive advantage and future earnings (Ref. 13). Researchers have found that by the time children reach 11 or 12 years of age, they are decoding consumption symbols based on brand names, forming impressions of product owners based on the image and meanings of the brand name identified with the product (Ref. 14).

As new marketing restrictions under the reissued final rule go into effect, the incentive to use other means such as brand name extension increases. Experience shows that, when faced with restrictions on marketing and advertising, tobacco firms shift their promotional efforts away from restricted practices and into a different mix of activities that are permissible (Ref. 15).

In light of the new regulations restricting the sale and distribution of cigarettes and smokeless tobacco products, one possible way for a tobacco company to attempt to gain immediate cachet with the youth market would be to purchase or license the name of a nontobacco product that has already established brand equity with youth. As FDA explained in issuing the original version of the rule, the restriction on the use of a nontobacco brand name sought to limit the elements of marketing and advertising “that resonate most strongly with the needs of those under 18 to establish an appropriate image and to create a sense of acceptance and belonging.” 61 FR 44396 at 44444 (1996). For example, the name of a popular motorcycle or cosmetic brand, if used on a tobacco product, may create immediate interest and appeal in the youth market. This would allow the tobacco companies to again capitalize on the susceptibility of this age group to certain advertising and marketing practices, and to the appeal of brands in

particular. Accordingly, the proposed restriction on the use of nontobacco product names is one means of preventing tobacco companies from circumventing the sale and distribution restrictions implemented in the reissued 1996 final rule.

As amended, the brand name provision permits tobacco products sold on or before the June 22, 2009, the date of enactment of the Tobacco Control Act, to continue to be marketed with their current brand name. This change in date restores the prospective intent of the 1996 provision. Further, neither the reissued 1996 final rule, nor the proposed amendment, would affect any aspect of marketing; the only effect of the proposed rule change would be to allow some additional brand names that are not allowed under the reissued 1996 final rule. Finally, requiring companies, when introducing new tobacco products, to research other uses of the same brand name is reasonable and does not significantly affect the way companies can introduce new tobacco products.

In addition, by amending the rule to allow tobacco companies to continue to use the trade or brand name of its cigarette or smokeless tobacco product after that brand name is later registered by another company with the USPTO or used on a nontobacco product, FDA seeks to prevent companies who manufacture products other than tobacco from unfairly exploiting the rule to the detriment of tobacco companies. Accordingly, once a tobacco product is introduced to the market under a particular brand name, the subsequent introduction of a nontobacco product under the same name, or the registration of that brand name for a nontobacco product, would not make the continued marketing of the tobacco product under the same brand name a violation of this rule.

Furthermore, by amending the rule to allow manufacturers to seek an exemption from the restriction upon a demonstration that the proposed name does not have substantial appeal to children or adolescents, FDA seeks to target the restriction to achieve the specific intended goal.

II. Legal Authority

FDA's authority to issue this proposed rule is provided by section 102 of the Tobacco Control Act. Sections 102(a)(3) and (a)(4) provide that FDA may amend the reissued 1996 final rule in accordance with the Administrative Procedure Act requirements for notice and comment rulemaking (chapter 5 of title 5 of the United States Code). In addition, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act.

III. FDA Enforcement of the Brand Name Provision

On May 7, 2010, FDA announced the availability of the guidance entitled "Enforcement Policy Concerning Certain Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco" (75 FR 25271, May 7, 2010). Persons with access to the Internet may obtain an electronic version of that guidance document at either <http://www.regulations.gov> or <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>. FDA issued the guidance in part because it was aware of concerns regarding § 1140.16(a). The guidance discusses FDA's enforcement discretion policy concerning § 1140.16(a) while it considers what changes to the section, if any, would be appropriate to address those concerns. Specifically, the guidance provides that FDA intends to exercise its enforcement discretion concerning § 1140.16(a) not to commence enforcement actions under this provision where: (1) The trade or brand name of the cigarettes or smokeless tobacco product was registered, or the product was marketed, in the United States on or before June 22, 2009; or (2) The first marketing

or registration in the United States of the tobacco product occurs before the first marketing or registration in the United States of the nontobacco product bearing the same name; provided, however, that the tobacco and nontobacco product are not owned, manufactured, or distributed by the same, related, or affiliated entities including as a licensee.

IV. Environmental Impact

FDA has carefully considered the potential environmental impacts of this rule and determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule would not impose any direct or indirect costs on industry or government, but rather would only change the date on which products were exempted from complying with the brand name prohibition in the reissued 1996 final rule and ensure that cigarette and smokeless tobacco brands

may continue to use a trade or brand name that is subsequently used, or subsequently registered for use, on a nontobacco product, the Agency proposes to certify that the rule would not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

A. Affected Products

FDA has identified 17 cigarette and smokeless tobacco products that are out of compliance with § 1140.16(a) of the reissued 1996 final rule, which became effective on June 22, 2010, but that would be in compliance under the proposed amendment. These products were introduced between January 1, 1995 (the date when products were grandfathered in under the 1996 final rule), and June 22, 2009 (the grandfather date set forth in this proposed amendment), and they share names with nontobacco products presently registered with the USPTO.³ The 17 product names appear in table 1 of this Federal Register document.⁴

³ Registrations were current as of September 22, 2010.

⁴ There are additional tobacco products that share names with nontobacco products whose names are not registered with the USPTO.

⁵ NSDUH is a large, nationally representative survey conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA). While its primary purpose relates to drug use in the United States, it also provides information regarding cigarette use. Individuals aged 12 and above who had smoked within the past month were asked about their usual brand choice during that time period. The data indicate that the top 10 brands account for the usual choice of over 80 percent of respondents, with shares ranging from 42.4 percent for Marlboro to 1.9

Table 1.--Products Affected by the Proposed Rule

Cigarette or Smokeless Tobacco Brand	Year of Introduction	Examples of Nontobacco Products with Same Name**
Complete	2004	Golf Balls, Disposable Adult Briefs and Underwear
Eclipse	1996	Insect Traps, Oxygen Concentrators for Medical Use
Exact	2001	Ink and Toner, Medical and Surgical Instruments
Exalt*	2001	Display Racks, Cattle Vaccines
Grand Prix*	2008	Apparel for Horseback Riding, Car Wash Services
Kayak*	1999	Internet Travel Services, Protective Swimming Pool Liners
King's	1995	All-Purpose Flour, Safety Apparatus
Lone Star	2002	Welding Machines, Beer
Longhorn*	2003	Investment and Financial Services, Apparel
Premis	2004	Integrated Circuits, Hospital Accounting Software
Pro*	2008	Bicycles and Bicycle Accessories, Fireworks
Quest	2003	Software, Snowboards
Revel*	2001	Loudspeakers, Bedding and Bathroom Accessories
Roger	1999	Apparel, Pilot Training Services
Stonewall*	2001	Concrete Blocks for Retaining Walls, Turf and Herbicide
Tahoe	2000	Cookies, Hearth and Fireplace Products
Thunder	2009	Earmuffs, Potato Chips

* Smokeless Tobacco Product.

** List is not exhaustive.

Sources: Refs. 16 through 22.

Table 1 includes 10 cigarette brands. Data from the 2005 National Survey on Drug Use and Health (NSDUH) indicate that each of the 9 cigarette brands in this list that had been introduced by 2005 was the usual cigarette choice for less than (probably significantly less than) 1.9 percent of smokers (Ref. 23).⁵ Results from the 2008 Maxwell Reports, the primary private source of cigarette sales data, are consistent with those from the NSDUH (Ref 24).⁶ There are no

percent for Salem and USA Gold. None of the brands listed in table 1 appears in the list of top 10 brands. Accordingly, the shares must be less than 1.9 percent, and we believe that the shares are likely substantially less than that given the brands' relative obscurity.

⁶ Maxwell lists 2008's 14 highest-selling cigarette brands, the smallest of which (Misty) had a 1.4 percent market share (4.87 billion units sold). Since none of the brands appearing in table 1 are among the top 14 ranked by Maxwell, each would have had a market share no higher than 1.4 percent.

⁷ Most of the nontobacco products with which they share names (examples are listed in table 1) are not widely-recognized consumer products and lack strong brand equity; consequently, consumers, including youth, are not likely to identify the nontobacco product names with particular brand images, much less be motivated by them to initiate or continue tobacco use.

⁸ If a discontinued product has a low sales volume, there are a large array of similar products on the market to which consumers could switch.

reported data indicating that any of the brands listed in table 1 are brands popular with youth. Several sources agree that the most popular brands among youth are Marlboro, Newport, and Camel (Refs. 23 and 25).

Table 1 includes seven smokeless tobacco brands. Five of them were introduced before 2005. The 2005 NSDUH identifies the 15 brands used most often by past-month smokeless tobacco users (Ref. 26). The only brand from table 1, among the five introduced prior to 2005, reported separately in the NSDUH data is Longhorn, which had an overall share of 0.7 percent. Among persons aged 12 to 17, it had a share of only 0.4 percent. The remaining brand shares were too small to be reported individually.

B. Benefits of the Proposed Rule

The proposed rule would allow the manufacturers of cigarettes and smokeless tobacco products listed in table 1 of this Federal Register document to avoid incurring the costs associated with changing their products' names. Relevant types of costs may include label redesign, market-testing new names, and additional promotional spending to inform customers of name changes. Furthermore, because the proposed amendment ensures that manufacturers may continue to use a trade or brand name for their tobacco product even if that name is subsequently used or registered for use with the USPTO, it would allow an unknown number of additional producers to avoid these name change costs.

Another benefit of the rule accrues to consumers of tobacco products that are out of compliance with the reissued 1996 final rule but are not profitable enough to justify the cost of a name change. Without this proposed amendment, such products could be discontinued and their consumers (other than those who quit using tobacco products) would have to switch to less-preferred brands.

C. Costs of the Proposed Rule

The costs imposed on society by the proposed rule can take the following forms: (1) Reduced producer profits (sales revenues minus production cost) that are not offset by increased profits of other firms or (2) losses borne by consumers. Costs in the form of reduced producer profits are likely to be zero since the proposed amendment would allow firms to avoid incurring production costs associated with renaming their products (as discussed in section V.B of this Federal Register document) and the proposed amendment would not change total sales of cigarettes and smokeless tobacco products (though sales may shift between particular brands as discussed in section V.D of this Federal Register document).

Losses borne by consumers take the form of health and life expectancy effects. To the extent that (a) young people initiate tobacco use based on imagery from nontobacco products that share brand names with cigarettes and smokeless tobacco and (b) current users of these products continue consuming tobacco due only to brand loyalty, morbidity and mortality will increase, most notably among those new tobacco users but also among individuals exposed to passive smoking. FDA anticipates, however, these types of costs due to changing the grandfather date will be negligible since sales of the affected tobacco products are low overall and are expected to remain low in the future.⁷ Moreover, given the addictive nature of tobacco and the lack of strong brand imagery associated with the affected products, brand loyalty is unlikely to be a primary factor in the continuance of tobacco consumption by established users of these products. Thus, FDA estimates the total cost of the proposed amendment to be near zero.

D. Distributional Effects of the Proposed Rule

In the absence of the proposed amendment, name changes would be required for the 17 products listed in table 1 of this Federal Register document. If current consumers of these

products do not switch to the renamed products, it is likely, given the addictive nature of tobacco, that at least some would start consuming other brands of cigarettes or smokeless tobacco.⁸ The amendment, by preventing this shift in sales, maintains value for the producers of table 1 products, instead of transferring value to producers of substitute products as would occur under the rule as originally published.

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to “construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” Section 916(a)(2) of the FD&C Act (21 U.S.C. 387p) expressly preempts any State or local requirement “which is different from, or in addition to, any requirement under [Chapter IX of the FD&C Act] relating to”, among other things, misbranding. This express preemption provision, however, “does not apply to requirements relating to” among other things “the sale, distribution, * * * access to, [or] the advertising and promotion of, * * * tobacco products.” If this proposed rule is made final, the final rule would modify the existing restrictions on the sale and distribution of cigarettes and smokeless tobacco products. The failure to comply with those restrictions, as modified, renders the product misbranded under the FD&C Act.

VII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Requests for Comments

FDA is requesting comments on this proposed rule. In drafting this proposal, FDA was aware of concerns that had been raised by § 1140.16(a) of the reissued 1996 final rule, including claims raised in litigation brought in federal district court challenging the constitutionality of the rule. After considering these concerns and claims, FDA is proposing to narrow the scope of the existing rule.

The current rule is intended to ensure that other restrictions on the sale and distribution of cigarettes and smokeless tobacco products to children and adolescents are not undermined by a tobacco manufacturer attempting to exploit the imagery or consumer identification attached to a nontobacco product. We request comments, including any data or information, on whether the proposal adequately addresses this goal, including topics such as the importance of brand names to children and adolescents, criteria FDA could use to evaluate whether a particular brand name has appeal to children and adolescents and under what circumstances a brand name might acquire appeal to children and adolescents, the vulnerability of children and adolescents to targeted marketing strategies, and instances where brand names have been used to attract the youth market.

With respect to the request for exemption process in proposed § 1140.16(a)(3), the Agency requests comments on the standard manufacturers should be required to meet to qualify for the exemption (whether substantial appeal to youth or some other standard), as well as the

criteria and specific types of information that should be required to demonstrate that a name does not exceed the standard in its appeal to youth. FDA also requests comments on alternative approaches to narrowing the restriction, such as prohibiting use of a registered nontobacco brand name on a tobacco product only if such name is registered to the same, related, or affiliated entity or is used under a licensing agreement (under the assumption that non-affiliated companies would protect their registered brand names that have strong imagery or consumer identification). If you suggest this or an alternative approach, you should address the basis for the limitation, such as by providing data or information showing how this limitation will ensure that manufacturers do not exploit the imagery or consumer identification attached to a nontobacco product.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday. (FDA has verified Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. Centers for Disease Control and Prevention, "Tobacco Use Among Middle and High School Students--United States, 2000-2009," Morbidity and Mortality Weekly Report, 59(33); 1063-1068, August 27, 2010, available at

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5933a2.htm>.

2. Centers for Disease Control and Prevention, "Trends in Smoking Initiation Among Adolescents and Young Adults--United States, 1980-1989," Morbidity and Mortality Weekly Report, 44(28); 521-525, July 21, 1995, available at

<http://www.cdc.gov/mmwr/preview/mmwrhtml/00038190.htm>.

3. Centers for Disease Control and Prevention, "Youth Risk Behavior Surveillance--United States, 2009," Morbidity and Mortality Weekly Report, 59 (No. SS-5): June 4, 2010, available at <http://www.cdc.gov/mmwr/pdf/ss/ss5905.pdf>.

4. Johnston, L.D., et al., "Smoking Continues Gradual Decline Among U.S. Teens, Smokeless Tobacco Threatens a Comeback," University of Michigan News Service: Ann Arbor, MI, December 14, 2009, available at

<http://www.monitoringthefuture.org/data/09data.html#2009data-cigs>.

5. Centers for Disease Control and Prevention, "Tobacco Use and the Health of Young People," July 5, 2011, available at <http://www.cdc.gov/HealthyYouth/tobacco/facts.htm>.

6. 1994 Institute of Medicine, *Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths*, Washington, DC: National Academy Press (1994), ("[T]obacco advertising and promotion undoubtedly contribute to the multiple and convergent psychosocial influences that lead children and youths to begin using these products and to become addicted to them.")

7. Finding 2673, United States v. Philip Morris, 449 F. Supp 2d 1, 990 (D.D.C. 2006) (“[M]arketing has been and continues to be enormously effective in influencing young people to smoke.”), aff’d in relevant part, 566 F.3d 1095 (D.C. Cir. 2009) (per curiam), cert. denied, 130 S. Ct. 3501 (2010).
8. Shadel, W.G. and Tharp-Taylor, S., “How Does Exposure to Cigarette Advertising Contribute to Smoking in Adolescents? The Role of Developing Self-Concept and Identification With Advertising Models,” Addictive Behavior, 34(11); 932-937, November 2009.
9. Krugman, Dean M., et al., “Understanding the Role of Cigarette Promotion and Youth Smoking in a Changing Marketing Environment,” Journal of Health Communications, 10:261-278, 2005 (“Advertising and promotion continue to play an important role in selling cigarettes to youth even after the 1998 MSA [Master Settlement Agreement].”)
10. Henriksen, Lisa, et al., “A Longitudinal Study of Exposure to Retail Cigarette Advertising and Smoking Initiation,” Pediatrics, 126(2); 232-238, August 2010, available at <http://pediatrics.aappublications.org/cgi/content/abstract/126/2/232>.
11. Federal Trade Commission Cigarette Report for 2007 and 2008 (issued 2011), available at <http://www.ftc.gov/os/2011/07/110729cigarettereport.pdf>, and Federal Trade Commission Smokeless Tobacco Report for 2007 and 2008 (issued 2011), available at <http://www.ftc.gov/os/2011/07/110729smokelesstobaccoreport.pdf> (In 2008, the tobacco industry spent \$9.94 billion on advertising and promotion of cigarettes, and another \$547.9 million for smokeless tobacco products.)
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- List of Subjects in 21 CFR Part 1140
- Advertising, Labeling, Smoking, Tobacco.
- Therefore, under the Federal Food, Drug, and Cosmetic Act, as amended by section 102 of the Tobacco Control Act, and under the authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1140 be amended as follows:

PART 1140--CIGARETTES AND SMOKELESS TOBACCO

1. The authority citation for 21 CFR part 1140 reads as follows:

Authority: 21 U.S.C. 301 et seq., Sec 102, Pub. L. 111-31, 123 Stat. 1776.

2. In § 1140.16, revise paragraph (a) to read as follows:

§ 1140.16 Conditions of manufacture, sale, and distribution.

(a) Restriction on product names. (1) Except as provided in paragraph (a)(2) or (a)(3) of this section, a manufacturer shall not use a trade or brand name for a cigarette or smokeless tobacco product if that name was registered with the United States Patent and Trademark Office for a nontobacco product on the date the tobacco product was first sold in the United States.

(2) Paragraph (a)(1) of this section does not apply to a cigarette or smokeless tobacco product sold on or before June 22, 2009.

(3) A manufacturer may request an exemption from the restriction on use of a trade or brand name in paragraph (a)(1) of this section. Such request must be in writing to the Director of the Center for Tobacco Products and contain sufficient information to demonstrate that the trade or brand name that is registered for a nontobacco product does not, based on its use for the nontobacco product, have a substantial appeal to children or adolescents.

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Dated: November 10, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.